UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
***Johns v. CR Bard et al*,**
Case No. 2:18-cv-1509

EVIDENTIARY MOTIONS OPINION AND ORDER NO. 11

This Opinion addresses Plaintiff's Motion to Exclude the Opinions and Testimony of Defense Expert Robert D. Tucker, Ph.D., M.D. (ECF No. 42) and Plaintiff's Motion to Exclude the Opinions and Testimony of Defense Expert James M. Anderson, M.D., Ph.D. (ECF No. 399). For the reasons that follow, both motions are **GRANTED IN PART AND DENIED IN PART**.

I. Background[1]

This case is the first bellwether trial, selected from thousands of cases in this multidistrict litigation ("MDL"), alleging "that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions." *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1 (S. D. Ohio Sept. 1, 2020). This includes the Ventralight ST, the device implanted in Plaintiff. The Ventralight ST is a prescription medical device used for hernia repairs. The Food and Drug Administration ("FDA") cleared it for use through the premarket notification

[1] The Court assumes that the parties and other interested readers are familiar with the history of this case. For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order, *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1–6 (S.D. Ohio Sept. 1, 2020).

510(k) process in 2010 and later cleared it for use with the Echo Positioning System in 2011. The Ventralight ST is a multicomponent device made of a mesh that consists of polypropylene, polyglycolic acid fibers, and a bioresorbable hydrogel coating called "Sepra Technology" ("ST"). The ST-coated side of the mesh is placed against organs, such as the bowels, while the uncoated polypropylene side is placed against the fascia because the uncoated side maximizes tissue attachment, thus supporting the hernia repair. *Id.* at *1–2.

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of Defendants' allegedly defective Ventralight ST device. *Id.* at *4. The crux of Plaintiff's claims is that the ST coating on the Ventralight ST resorbs too quickly. *Id.* at *13. This leads to the premature exposure of bare polypropylene to internal organs and tissues, increasing the risk of potential complications. Plaintiff alleges that this occurrence led to omental adhesions after his laparoscopic hernia repair surgery in 2015. Plaintiff asserts that Defendants knew that polypropylene is unsuitable for permanent implantation in the human body. *Id.* at *2–4. The following claims remain for trial: design defect, under negligence and strict liability theories; failure to warn, under negligence and strict liability theories; breach of express warranty; breach of implied warranty; breach of implied warranty of merchantability; negligent misrepresentation; and punitive damages. *Id.* at *6–25. Now, various evidentiary motions are ripe for adjudication.

II. Legal Standard

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is

to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975) ("A better practice is to deal with questions of admissibility of evidence as they arise."). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (quoting *Ind. Ins. Co*., 326 F. Supp. 2d at 846). The denial, in whole or in part, of a motion in limine does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

The burden is on the party offering the expert testimony to demonstrate by a preponderance of proof that the opinions of their experts are admissible. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001). Any doubts regarding the admissibility of an expert's testimony should be resolved in favor of admissibility. *See Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) ("The Court [in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993),] explained that Rule 702 displays a 'liberal thrust' with the 'general approach of relaxing the traditional barriers to "opinion" testimony.'" (quoting *Daubert*, 509 U.S. at 588)); Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("A review of the case law after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.").

III. Analysis

Expert testimony, *i.e.* testimony given by "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education," is admissible if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. In this circuit, "[t]he Rule 702 analysis proceeds in three stages." *United States v. Rios*, 830 F.3d 403, 413 (6th Cir. 2016). "First, the witness must be qualified by 'knowledge, skill, experience, training, or education.' Second, the testimony must be relevant, meaning that it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' Third, the testimony must be reliable." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008) (quoting Fed. R. Evid. 702).

First, an expert witness must be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "[T]he issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question." *Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020) (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). "[T]he only thing a court should be concerned with in determining the qualifications of an expert is whether the expert's knowledge of the subject matter is such that his opinion will likely assist the trier of fact in arriving at the truth. The weight of the expert's testimony must be for the trier of fact." *Mannino v. Int'l Mfg. Co.*, 650 F.2d 846, 851 (6th Cir. 1981). A party's expert need only meet the "'minimal qualifications' requirement—not one who could teach a graduate seminar on the subject." *Burgett*

v. Troy-Bilt LLC, 579 F. App'x 372, 377 (6th Cir. 2014) (quoting *Mannino*, 650 F.2d at 851); *see also Dilts v. United Grp. Servs., LLC*, 500 F. App'x 440, 446 (6th Cir. 2012) ("An expert's lack of experience in a particular subject matter does not render him unqualified so long as his general knowledge in the field can assist the trier of fact.").

Second, expert testimony must be relevant. Expert testimony is relevant if it will "help the trier of fact to understand the evidence or to determine a fact in issue." *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 208 (6th Cir. 2015) (quoting *United States v. Freeman*, 730 F.3d 590, 599–600 (6th Cir. 2013)); Fed. R. Evid. 702(a). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993) (quoting 3 J. Weinstein & M. Berger, Weinstein's Evidence ¶ 702[02], p. 702–18 (1988)). "This requirement has been interpreted to mean that scientific testimony must 'fit' the facts of the case, that is, there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify." *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (citing *Daubert*, 509 U.S. at 592). This is a case specific inquiry. *Madej*, 951 F.3d at 370. ("Whether an opinion 'relates to an issue in the case' or helps a jury answer a 'specific question' depends on the claims before the court.").

Third, expert testimony must be reliable. Rule 702 provides the following general standards to assess reliability: whether "the testimony is based on sufficient facts or data," whether "the testimony is the product of reliable principles and methods," and whether "the expert has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702(b)–(d). To evaluate the reliability of an opinion, courts also consider "'testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community,'" though these "factors 'are not

dispositive in every case' and should be applied only 'where they are reasonable measures of the reliability of expert testimony.'" *In re Scrap Metal*, 527 F.3d at 529 (citations omitted); *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) (describing these factors as "flexible" (quoting *Daubert*, 509 U.S. at 594)). The objective of the reliability requirement is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152.

Plaintiff seeks to exclude the opinions and testimony Dr. Robert D. Tucker, M.D., Ph.D. and Dr. James M. Anderson, M.D., Ph.D.

A. Robert D. Tucker, M.D., Ph.D.

Dr. Tucker is a pathologist and a researcher in biomedical studies, biomedical engineering, and minimally invasive surgeries. (ECF No. 42-1 at PageID #2337.) Plaintiff argues that four of Dr. Tucker's opinions should be excluded. He challenges Dr. Tucker's (1) causation opinions, (2) FDA opinions, (3) pore size opinions, and (4) Material Safety Data Sheet ("MSDS") opinions. At this time, Dr. Tucker's FDA and MSDS opinions are inadmissible.

1. Causation opinions

Plaintiff asserts that Dr. Tucker's causation opinions are unreliable specific causation opinions (ECF No. 42 at PageID #2325–27; ECF No. 104 at PageID #7182–83) and that Dr. Tucker is unqualified to offer any causation opinions, whether general or specific (ECF No. 104 at PageID #7182–83). Defendants argue that Dr. Tucker's opinions are general causation opinions that Dr. Tucker is qualified to offer. (ECF No. 87 at PageID #5891–92.) Dr. Tucker appears to offer general causation opinions, and he is qualified to do so.

First, the type of opinion Dr. Tucker offers. General causation evidence in this case

demonstrates that the Ventralight ST is capable of "caus[ing] the type of injury that a plaintiff alleges" and specific causation evidence shows that the Ventralight ST caused harm to Plaintiff. *Madej*, 951 F.3d at 369. A "differential diagnosis" or "diagnosis of exclusion" is "considered to be 'a standard scientific technique'" for an expert to determine specific causation. *Johnson v. Memphis Light Gas & Water Div.*, 695 F. App'x 131, 138 (6th Cir. 2017) (citations omitted); *see also In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, No. 2:18-cv-00136, 2019 WL 6894069, at *3 (S.D. Ohio Dec. 18, 2019) (noting this is an appropriate method for determining specific causation). A differential diagnosis does not speak to general causation. *See Kerner v. Terminix Int'l Co.*, No. 2:04-CV-735, 2008 WL 341363, at *4 (S.D. Ohio Feb. 6, 2008) (distinguishing caselaw addressing differential diagnoses because the expert offered a general causation opinion).

The source of contention is whether Dr. Tucker's use of the word "Plaintiffs" throughout his expert report connotes a specific causation opinion and whether Dr. Tucker must have performed a differential diagnosis, which Defendants do not dispute that he did not perform. In various instances he opines that "Plaintiffs'" injuries were not caused by the Ventralight ST but by preexisting conditions or that the device could not have caused "Plaintiffs'" injuries. (ECF No. 42-1 at PageID #2342.) These statements suggest a specific causation opinion. At the same time, Dr. Tucker uses "Plaintiffs" as a shorthand for the histology and pathology materials provided by counsel that he reviewed for this case. For example, he states, "[i]n my review of the pathology materials in this case, I saw no evidence of abnormal healing responses in connection with a mesh implant procedure for any Plaintiffs." (ECF No. 42-1 at PageID #2346.) In this context, Dr. Tucker's opinions appear to be general causation opinions.

Dr. Tucker's wording is unclear, but the Court cannot say with certainty that Defendants

could not offer Dr. Tucker's opinion testimony in an appropriate manner to prove general causation. At trial, Defendants must show that Dr. Tucker's opinion is a general causation opinion based on his review of the provided pathology and histology. Defendants purport to do so: "Dr. Tucker's opinions also arise out of his review and histopathologic evaluation of numerous specimens of explanted mesh/tissue materials," and "Dr. Tucker's report and opinions in this case are limited to general opinions." (ECF No. 87 at PageID #5891–92.) In any case, Dr. Tucker cannot opine about "Plaintiffs" as he did in his report because such statements are likely to confuse the jury or mislead them to interpret Dr. Tucker's testimony as specific causation evidence. And although Dr. Tucker's opinion is not inadmissible because he failed to conduct a differential diagnosis, Plaintiff may cross-examine Dr. Tucker about whether he sufficiently considered other causes of injury when he reviewed the pathologies of patients that he was presented with.

Next, qualifications. Dr. Tucker is qualified to offer general causation opinions. Dr. Tucker is an M.D. and Ph.D. with a medical and research specialty in pathology. (ECF No. 42-1 at PageID #2336–37.) He has ample experience with medical implantable devices and reviewing pathology slides and specimens. (*Id.* at PageID #2337.) Dr. Tucker's education and experience qualifies him to opine on the effect of the mesh devices on human tissues, specifically whether the tissues contained evidence of the mechanisms that caused Plaintiff's injuries or the injuries themselves, including poor tissue integration, degradation, mesh contraction, biocompatibility, adhesions, etc. *E.g.*, *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, 2020 WL 6605612, at *9 (S.D. Ohio Sept. 11, 2020) (concluding that medical doctors, *i.e.* those who or not engineers or biochemists, may be qualified "to opine on how the product reacts inside the body"). Because Dr. Tucker is qualified to opine on the reaction of tissues to mesh devices from a pathology perspective, Plaintiff's arguments that Dr. Tucker's lack of clinical

experience renders him unqualified are unpersuasive. (ECF No. 104 at PageID #7182–83.)

2. FDA opinions

Plaintiff argues that Dr. Tucker's opinions related to FDA approval and clearance of the Ventralex device and the Prolene suture are inadmissible under Federal Rule of Evidence 403 and that any representations that a device is safe because it was approved by the FDA via the 510(k) premarket notification process is unlawful under 21 C.F.R. § 807.97. (ECF No. 42 at PageID #2328–29.) The Court agrees that Dr. Tucker may not offer these opinions, but on different grounds. Dr. Tucker's opinions are irrelevant and inadmissible character evidence.

Opinions related to the Ventralex device and Prolene sutures are irrelevant, and Defendants agree. (ECF No. 87 at PageID #5892.) Neither is a predicate device to the Ventralight ST or directly connected to the Ventralight ST, such as serving as a component part. Although it appears that the Prolene suture is also made of polypropylene, there is no indication that the Prolene suture is a component part of the Ventralight ST or otherwise directly connected to the Ventralight ST. Dr. Tucker's discussion of the Ventralex's 510(k) clearance also focused on the Ventralex's expanded polytetrafluoroethylene ring—a feature that the Ventralight ST does not have. (ECF No. 42-1 at PageID #2339–40.) Therefore, evidence that the Ventralex received 510(k) clearance is irrelevant to the triable issues in this case, including the reasonableness of Defendants' conduct and knowledge regarding the Ventralight ST.

Even though Defendants appear to concede that these opinions are irrelevant, they also argue that Dr. Tucker's opinions related to the Ventralex device and Prolene sutures are "probative on issues of standard of care and the reasonableness of [Defendants'] actions." (ECF No. 87 at PageID #5893.) This is improper propensity evidence. In this MDL, evidence related to FDA compliance of other devices is impermissible character or propensity evidence under Federal Rule

of Evidence 404(b) if offered to prove FDA compliance with the Ventralight ST. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.* --- F. Supp. 3d ----, Nos. 2:18-md-2846, 2:18-cv-1509, 2021 WL 81821, at *3, 6–7 (S.D. Ohio Jan. 11, 2021). Defendants cannot rely on the premarket approval of other devices, particularly where the devices are not predicates to or components of the Ventralight ST, to demonstrate that Defendants satisfied the standard of care when designing and marketing the Ventralight ST.

Defendants also state that Dr. Tucker's suggestions that "the FDA considers safety and efficacy of products submitted through the 510(k) process . . . aligns with recognized FDA guidance and legal principles." (ECF No. 87 at PageID #5892.) Evidence of the 510(k) process for the Ventralight ST is admissible in this case because it is part of the story of the Ventralight ST, but "[n]o experts will be permitted to opine on the background or legal meaning of the process." *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6603657, at *8 (S.D. Ohio Oct. 20, 2020).

3. Pore size opinions

Next, Plaintiff argues that Dr. Tucker's opinion that there is a lack of consensus about how to measure the pore size of mesh devices is unreliable, that he is unqualified to offer this opinion, and that this opinion is excludable under Rule 403. (ECF No. 42 at PageID #2329; ECF No. 104 at PageID #7182). The Court disagrees because the opinion that Dr. Tucker actually offers, as opposed to Plaintiff's characterization of his opinion, is not misleading and is reliable, and he is qualified to offer it.

As an initial matter, Plaintiff misconstrues Dr. Tucker's pore size opinion. Dr. Tucker opines that there are different methods for measuring pore size and that the FDA has not selected a standard method for measuring pore size, leading to inconsistencies in medical and scientific

literature discussing pore size. (ECF No. 42-1 at PageID #2351–52; ECF No. 42-4 at PageID 2417.) Plaintiff characterizes Dr. Tucker's opinion as one that "the only testing that should be conducted . . . is the testing required by the FDA," and that the FDA has determined that there is no need for a standard measure of more size. (ECF No. 42 at PageID #2329–30.) This is simply not borne out by Dr. Tucker's report or testimony. Dr. Tucker refused during testimony to opine whether it was appropriate for companies to go beyond the requirements of the 510(k) rules and conduct additional testing on pore size. (ECF No. 42-4 at PageID #2417–18.) Plaintiff also argues that Dr. Tucker cannot offer a reliable opinion "on the most accurate way to measure pore size." (ECF No. 104 at PageID #7182.) But the point of his opinion is that there is no consensus on how to measure pore size in mesh devices. Accordingly, Plaintiff's arguments that Dr. Tucker's opinion is misleading and thus inadmissible under Rule 403 are unpersuasive.

Dr. Tucker's opinion that there is no consensus in the literature regarding pore size measurement is reliable. Dr. Tucker reviewed medical literature to reach this conclusion. (ECF No. 42-1 at PageID #2325 &n.4; #2352 & n.7.) Because this opinion is about a lack of consensus in medical literature (ECF No. 42-1 at PageID #2351), the most reliable basis for that opinion is a review of the literature, *see In re Scrap Metal*, 527 F.3d at 529 (noting that the reliability inquiry should focus on "reasonable measures of the reliability of expert testimony").

Plaintiff's counterarguments go to weight, not admissibility. Plaintiff contends that Dr. Tucker did not "process" the slides himself and that he did not review the entire explant in addition to the slides while forming his opinions (ECF No. 104 at PageID #7184.) But this does not demonstrate that Dr. Tucker's opinion about the status of medical literature is unreliable. Nor does the fact that Dr. Tucker did not create the pathology slides render unreliable Dr. Tucker's opinion that in light of the lack of consensus, Defendants' measure of pore size in the Ventralight ST was

appropriate. (ECF No. 4201 at PageID #2352.) Weaknesses in methodology are issues of weight, not admissibility, best addressed during cross examination. *Johnson*, 695 F. App'x at 142 (quoting *Best*, 563 F.3d at 179); *see also Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

Finally, Plaintiff also appears to argue that Dr. Tucker is unqualified to offer any pore size opinions because "[h]e lacks first-hand knowledge of the pore sizes in mesh," meaning he has never explanted or implanted a mesh device. (ECF No. 104 at PageID #7182.) However, Dr. Tucker's opinions about pore size ultimately go to tissue integration with the surrounding the mesh, including the ability of cells to penetrate the mesh through the pores "as part of the normal wound healing process." (ECF No. 42-1 at PageID #2350–52.) As a pathologist, Dr. Tucker is qualified to offer opinions that go to tissue responses.

4. MSDS opinions

Finally, Plaintiff argues that Dr. Tucker's opinions addressing the Marlex and Pro-Fax polypropylene MSDSs are unreliable. (ECF No. 42 at PageID #2330–31.) In his report, Dr. Tucker asserts that "[t]he warnings in the MSDS are not intended for the final mesh product" and that there is no scientific support for the MSDS statement that the polypropylene is unsuitable for permanent human implantation. (ECF No. 42-1 at PageID #2359–60.) There is no need to consider whether these opinions are reliable because, considering the Court's earlier ruling on the Marlex MSDS, Dr. Tucker's MSDS opinions are irrelevant.

Here, the Marlex MSDS is admissible as evidence of Defendants' knowledge of the risks presented by polypropylene and inadmissible hearsay if offered to demonstrate that polypropylene was unsafe for permanent implantation in the human body. *In re Davol, Inc./C.R. Bard, Inc.*, 2020

WL 6603657, at *4–5. Therefore, Dr. Tucker's opinion as to the meaning of the MSDSs, specifically that they are not indicative of safety for consumers or end users and that they are unsupported scientifically, is irrelevant to any question before the jury.

B. James M. Anderson, M.D., Ph.D.

Dr. Anderson is a pathologist and a researcher in biomaterials, medical devices, and prostheses. (ECF No. 399-1 at PageID #21222–23.) Plaintiff argues that (1) Dr. Anderson's opinions are all generally irrelevant and are all unreliable, (2) Dr. Anderson should be precluded from offering specific causation opinions, (3) Dr. Anderson's ST coating resorption opinion is unreliable, (4) Dr. Anderson's MSDS opinion is unreliable, and (5) Dr. Anderson is unqualified to offer opinions about surgical techniques. Part of Dr. Anderson's ST coating resorption opinions and his MSDS opinions are inadmissible.

1. General relevance and reliability

Plaintiff argues that all of Dr. Anderson's opinions are irrelevant because Dr. Anderson's opinions relate only to the plaintiff in *McCourt* (ECF No. 399 at PageID #21209; ECF No. 418 at PageID #22216) and that all are unreliable because Dr. Anderson did not specify his methodology (ECF No. 418 at PageID #22216). The Court disagrees; Dr. Anderson offers relevant general opinions in his report, *i.e.* opinions that are not limited to Mr. McCourt, and it is premature to address Plaintiff's general reliability arguments.

At best, Plaintiff demonstrates doubt regarding whether Dr. Anderson's opinion is limited to Mr. McCourt, and doubt about the admissibility of an expert's testimony must be resolved in favor of admissibility. *See Jahn*, 233 F.3d at 388. As Plaintiff points out, Dr. Anderson's testimony during his deposition about the scope of his opinions is admittedly contradictory. He first stated that his opinions "refer to Mr. McCourt's case." (ECF No. 399-2 at PageID #21273.)

Then Dr. Anderson explained, "Well, no. I mean, Mr. McCourt received [the] Ventralight ST. My opinion also speaks to the Ventralight ST." (*Id.*) But when counsel asked, "So your report contains all your opinions in the cases in which you were disclosed this litigation," Dr. Anderson replied, "No, they refer to the McCourt case only." (*Id.* at PageID #21274.) However, Dr. Anderson's expert report unambiguously contains relevant general opinions, such as that polypropylene is biocompatible and that the Ventralight ST had adequate pore size for proper tissue integration. (ECF No. 399-1 at PageID #21225–300.) Moreover, Defendants have been consistent in their position that Dr. Anderson will be offered only as a general witness. (ECF No. 409 at PageID #21477.) Dr. Anderson's report tips the scales in favor of admission of his opinions at this time, although some of his testimony may be an appropriate topic for cross examination.[2]

Plaintiff also argues that Dr. Anderson's "application of Plaintiff McCourt's pathology to the *Johns* case is . . . irrelevant." (ECF No. 399 at PageID #21212.) But Dr. Anderson's review of Mr. McCourt's pathology is relevant to the extent Dr. Tucker's relevant, general Ventralight ST opinions draw on his review of Mr. McCourt's pathology. Importantly, though, Dr. Tucker may not refer to Mr. McCourt as a plaintiff in this MDL; in this context, Mr. McCourt's pathology is simply another data point. Defendants have stated that Dr. Anderson will not specifically mention Mr. McCourt. (ECF No. 409 at PageID #21483.)

Finally, the Court cannot constructively address Plaintiff's argument that Dr. Anderson's opinions are generally unreliable. Plaintiff asserts tersely in his reply brief that "Defendants do not explain in their Opposition what Dr. Anderson's methodology was in formulating *any* of his

[2] Plaintiff claims here that Dr. Anderson's report is a recitation of his opinions in the transvaginal pelvic mesh MDL and that he spent too few hours forming his opinions in this case. (ECF No. 399 at PageID #21210.) Dr. Anderson may draw on his work from previous litigation to form his opinions—if his opinions are otherwise reliable. *See In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6605542, at *20 (S.D. Ohio Sept. 1, 2020). That Dr. Anderson relies heavily on his previous litigation experience goes to the weight of the expert testimony, which is an issue for the jury. These issues can be addressed during cross examination.

opinions nor do they provide the general framework he used in formulating his opinions." (ECF No. 418 at PageID #22216.) Defendants have not had the opportunity to respond to Plaintiff's broader reliability argument because it was not raised until his reply brief. Therefore, the Court declines to address this argument before trial, without the benefit of developed argument from both sides. Because Plaintiff specifically argues that Dr. Anderson's ST coating resorption and MSDS opinions are unreliable, the Court addresses these particular reliability issues *infra*.

2. Specific causation opinions

Next, Plaintiff contends that Dr. Anderson cannot offer specific causation opinions. (ECF No. 399 at PageID #21215–16.) Defendants confirm that they do not intend to have Dr. Anderson offer specific causation opinions (ECF No. 409 at PageID #21477), which Plaintiff acknowledges (ECF No. 399 at PageID #21215.) Accordingly, this argument is moot.

3. ST coating resorption opinions

Next, Plaintiff argues that Dr. Anderson's opinions related to the window of time in which the ST coating was resorbed are irrelevant and unreliable. (ECF No. 399 at PageID #21210.) Dr. Anderson's opinions about the resorption of the ST coating are relevant, and his opinion that the ST coating performed as designed based on his visual examination of Mr. McCourt's slides is also reliable. However, his opinions about the mindset of the pathologist who created Mr. McCourt's pathology slides and the inferences he draws from those opinions are unreliable.

As a preliminary matter, the parties disagree about the precise opinion that Dr. Anderson offers. Plaintiff focuses on Dr. Anderson's statement that the Ventralight ST's ST coating resorbed within 28 days (ECF No. 399 at PageID #21210–12), and Defendants point to his statement that the Ventralight ST behaved as it should by preventing and minimizing adhesions (ECF No. 409 at PageID #21485.) After reviewing his testimony, it is clear that Dr. Anderson referenced the 28-

day figure only because Plaintiff's counsel asked him about how an animal study affected Dr. Anderson's ST coating opinion. (ECF No. 409-4 at PageID #21616–18.) Dr. Anderson explained in the first instance that the animal study "confirmed my opinion about the resorption behavior in vivo of the Ventralight ST," specifically that "the device behaved as designed with minimal to no adhesions present." (*Id.* at PageID #21617.) Thus, the Court treats this statement as Dr. Anderson's opinion for the purposes of this analysis.[3]

First, relevance. Dr. Anderson's ST coating resorption opinions are relevant to Plaintiff's theory of injury—that the ST coating resorbed too quickly once implanted in Plaintiff, exposing bare polypropylene. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F. Supp. 3d. ----, Nos. 2:18-md-2846, 2:18-cv-01509, 2021 WL 486425, at *10 (S.D. Ohio Feb. 10, 2021). So long as Defendants offer Dr. Tucker's opinions as general opinions about the Ventralight ST, they are relevant even if they draw on the pathology from Mr. McCourt. *Supra*, Part III.B.1. And again, Defendants have stated that Dr. Anderson will not specifically mention Mr. McCourt. (ECF No. 409 at PageID #21483.)

Second, reliability. Dr. Anderson's ST coating resorption opinions are partly—but not all—impermissible speculation. Although "[t]rained experts commonly extrapolate from existing data . . . a Court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *Mitchell v. City of*

[3] Additionally, Plaintiff argues that Dr. Anderson's ST coating opinion was previously undisclosed. (ECF No. 399 at PageID #21210.) If Plaintiff sought to exclude this opinion because Defendants did not fulfill their duty under Federal Rule of Civil Procedure 26(a)(2)(B) to produce a complete expert report or Rule 26(e)(2) to supplement the report in light of Dr. Anderson's deposition testimony, the proper course of action was to file a motion to strike under Federal Rule of Procedure 37. *See, e.g.*, *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-cv-00915, 2:18-cv-01011, 2:18-cv-01320, 2:18-cv-01443, 2:18-cv-01022, 2020 WL 8707603 (S.D. Ohio Apr. 16, 2020) (granting in part Plaintiff's motion to strike Dr. Badylak's previously undisclosed opinion). The Court declines to consider excluding Dr. Anderson's ST coating opinion as a previously undisclosed opinion without the opportunity for full consideration of the issue.

Warren, 803 F.3d 223, 230–31 (6th Cir. 2015). Such is the case here. Dr. Anderson explained that because Mr. McCourt's slides "had no mesh," "the pathologist did not identify anything pathological with that specimen requiring him or her to submit tissues for slide preparation to identify any pathology." (ECF No. 399-2 at PageID #21266.) He opined that the "absence" of the mesh "is medical evidence that that pathologist did not find anything wrong with that product, and turned to submitting small bowel sections which were in the slide, but there was no indication of any adhesions in those tissue sections." (*Id.* at PageID #21266–67.) Dr. Anderson cannot speculate about the mindset of the pathologist that created the slides, including what the pathologist identified or did not identify, and especially whether the pathologist found anything "wrong" with the explanted Ventralight ST. *E.g.*, *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) (concluding that expert testimony "on the intent, motives or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise"); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009).

However, Dr. Anderson's opinion that the Ventralight ST prevented adhesions based on his visual examination of the slides, specifically his conclusion that no adhesions were present on the slides, is a reliable method of analysis given Dr. Anderson's expertise as a pathologist. (ECF No. 425 at PageID #22501 ("[I]n other mesh litigation, courts have expressly rejected arguments that visual observations . . . are unreliable methods."); *see also In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-4301, 2014 WL 186872, at *23 (S.D.W. Va. Jan. 15, 2014). Accordingly, this part of Dr. Anderson's ST coating resorption opinion is admissible.

Neither Plaintiff's nor Defendants' arguments to the contrary alter this conclusion. Plaintiff largely focuses on Dr. Anderson's speculation about the pathologist's mindset in creating the slides (ECF No. 399 at PageID #21211, 21213), but this speculation has no impact on Dr.

Anderson's visual analysis that there were no adhesions in the pathology slides. Plaintiff also argues that Dr. Anderson's opinion is irrelevant because Dr. Anderson never connected his review of Mr. McCourt's slides to Plaintiff's case. (*Id.* at PageID #21212.) However, Dr Anderson does not need to supply every link in the chain of Plaintiff's theory of the case for his opinion to be relevant. *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4536456, at *2–3 (S.D.W. Va. Aug. 30, 2016) ("A single expert need not provide all the pieces of the puzzle for their testimony to be useful to the jury in determining the ultimate issues in the case.").

On the other side, defendants argue that Dr. Anderson is not speculating due to his ample experience. (ECF No. 409 at PageID #21482, 21484.) Dr. Anderson's experience speaks to his qualifications, not the reliability of his opinion. And "'no matter how good' experts' 'credentials' may be, they are 'not permitted to speculate.'" *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 671 (6th Cir. 2010) (quoting *Goebel v. Denver & Rio Grande W. R.R. Co.,* 215 F.3d 1083, 1088 (10th Cir. 2000)). Defendants claim that the Court found Dr. Babensee's and Dr. El-Ghannam's general causation opinions reliable based on their experience (ECF No. 409 at PageID #21484), but in both of these instances the Court discussed their experience in relation to their qualifications—not the reliability of their opinions. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6605542, at *24–25 (S.D. Ohio Sept. 1, 2020) ("Dr. Babensee is well-qualified based on her knowledge, education, and experience as a biomaterials scientist to offer general opinions of the biological effects of the Ventralight ST mesh on the human body."); *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6603389, at *7 (S.D. Ohio Sept. 10, 2020) (concluding that Dr. El-Ghannam was qualified to offer his opinion and that even though his "experience is due to his work as an expert in other MDLs involving Bard's polypropylene devices

does not warrant exclusion of his opinions, as long as the opinions are sufficiently *reliable*" (emphasis added).)

4. MSDS opinions

Plaintiff challenges part of Dr. Anderson's report in which he addresses the MSDS as unreliable. (ECF No. 399 at PageID #21216.) In his report, Dr. Anderson characterizes the MSDSs as "safety documents for employees who handle raw materials" that "provide occupational exposure warnings." (ECF No. 399-1 at PageID #21247.) He also notes that the MSDSs do not indicate what testing and/or data supports the warning that polypropylene should not be used for permanent human implantation. (*Id.*) There is no need to address the reliability of Dr. Anderson's MSDS opinion because it is irrelevant and inadmissible. The Marlex MSDS is only admissible as evidence of Defendants' knowledge and is inadmissible hearsay if offered to demonstrate that polypropylene was unsafe for permanent implantation in the human body. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6603657, at *4–5. Therefore, Dr. Anderson's opinion regarding the meaning of MSDSs is irrelevant to what Defendants actually thought the MSDS meant or what they otherwise knew about the risks of the polypropylene at the time the Ventralight ST was designed and marketed. *Supra*, Part III.A.4.

5. Surgical technique opinions

Finally, Plaintiff argues that Dr. Anderson is unqualified to offer any opinions about surgical techniques used to implant the Ventralight ST because he is not a general surgeon and does not practice surgery. (ECF No. 399 at PageID #21216.) Defendants counter that Dr. Anderson is qualified to offer opinions about the impact of implantation technique on the body's response to implantation of the device. (ECF No. 409 at PageID #21489.) Dr. Anderson is qualified to opine on the impact of surgical technique on the body's tissue response.

As a pathologist, Dr. Anderson is qualified to testify about the effects of a particular surgical technique for placement of a mesh device on the body's tissue response. Dr. Anderson has forty-five years of experience studying biomaterials and medical devices, and their biocompatibility, tissue responses, and foreign body reactions. (ECF No. 399-1 at PageID #21223.) In his deposition, he explained that part of his study of biomaterials and medical devices involves animal implantations. (ECF No. 399-2 at PageID #21275.) In Dr. Anderson's report, he discusses factors that affect wound healing—a tissue response—including "physician factors." (ECF No. 399-1 at PageID #21240.) He explains that a surgeon's skills and training affect wound healing. (*Id.* at PageID #21241.) Dr. Anderson also explains that "appropriately implanted" mesh devices "lead[ ] to a decrease in the thickness of the mesh within the fibrous capsule as well as a decrease in the thickness of the fibrous capsule," which is a more positive outcome. (*Id.* at PageID #21245.) The impact of surgical techniques on tissue response is within his pathology expertise.

Plaintiff argues that because Dr. Anderson is not a surgeon, he cannot offer general surgery technique opinions. (ECF No. 399 at PageID #21217.) The Court generally agrees that Dr. Anderson is unqualified to offer surgery opinions from the perspective of the implanting surgeon. However, Dr. Anderson does not offer such an opinion; he opines on the impact of surgical methods from a pathology perspective. Plaintiff does not appear to dispute Dr. Anderson's qualifications as a pathologist. Indeed, Defendants expressly represent that they do not intend to have Dr. Anderson offer any surgery opinions. (ECF No. 409 at PageID #21489.)

IV. Conclusion

For these reasons, Plaintiff's motion to exclude Dr. Tucker's opinions and testimony (ECF No. 42) is **GRANTED IN PART AND DENIED IN PART**, and Plaintiff's motion to exclude Dr. Anderson's opinions and testimony (ECF No. 399) is **GRANTED IN PART AND DENIED IN PART**.

IT IS SO ORDERED.

6/28/2021
DATE

s/ Edmund A Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE